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PATENT
Attorney Docket No.: 021706-000810US

Assistant Commissioner for Patents
Washington, D.C. 20231

On May 17, 2004

TOWNSEND and TOWNSEND and CREW LLP

By: Sylvia Arnold



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Tony Wai-Chiu So et al.

Application No.: 10/124,197

Filed: April 16, 2002

For: PHARMACEUTICAL
COMPOSITION

Customer No.: 20350

Confirmation No. 1659

Examiner: Sharmila S. Gollamudi

Technology Center/Art Unit: 1616

DECLARATION UNDER 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Albert Zorko Abram, being duly warned that willful false statements and the like are punishable by fine or imprisonment or both, under 18 U.S.C. § 1001, and may jeopardize the validity of the patent application or any patent issuing thereon, state and declare as follows:

1. All statements herein made of my own knowledge are true and statements made on information or belief are believed to be true.
2. I am currently employed by Connetics Australia Pty Ltd, the assignee of the subject application.
3. I am a Senior Chemist –Technical IP Associate and have been in pharmaceutical research since 1987. I have been employed doing dermatological product development for the last 16 years. My *Curriculum Vitae* is of record.

4. I have reviewed and analyzed the above-referenced patent application, and I am familiar with the contents therein.
5. It is my understanding that the Examiner alleges in the Office Action dated October 17, 2003 that, in the Declaration under 37 C.F.R. § 1.132 submitted on April 1, 2003 ("the 2003 Declaration"), Applicants did not provide the identity and amount of the components in the inventive foam formulation used for the side-by-side comparison with the foam formulation of Di Schiena (U.S. Patent No. 4,866,067). For the reasons set forth herein, the Examiner's concerns are overcome.
6. As described in the 2003 Declaration, the formulation set forth in column 3, Example 3(e) of Di Schiena, entitled "Foam," was prepared in our laboratory at Connetics Australia following the teaching of Di Schiena with an understanding of the foam art.
7. Exhibit A contains a true copy of a page from a Connetics' laboratory notebook, with the date redacted therefrom. As shown in Exhibit A, the Di Schiena foam ("comparative") was prepared according to the teaching set forth in Example 3(e) of Di Schiena. An accepted hydrocarbon propellant (*i.e.*, Propellant P70) was substituted for the chlorofluorocarbon propellant of Di Schiena at an amount to produce a foam of acceptable quality (*see*, the 2003 Declaration).
8. The foam as disclosed in the subject application ("inventive") was prepared in our laboratory according to the following formulation:

Component	% w/w
Minoxidil	4.75
Ethanol	53.645
Purified Water	31.410
Butylated Hydroxytoluene	0.095
Lactic Acid (90%)	1.00
Citric Acid	0.10
Stearyl Alcohol	0.50
Cetyl Alcohol	1.10
Polysorbate 60	0.40
Propylene Glycol	2.00
Propellant P70	5.00
Total	100.00

9. Exhibit B contains a true copy of a page from my notebook, with the date redacted therefrom, disclosing the formulation set forth in the table above.
10. As described in the 2003 Declaration, I have performed a side-by-side comparison of the inventive foam against the comparative foam and found unexpected properties in the

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inventive foam that were not present in the comparative foam, including foam consistency, stability, and advantageous mechanical shear properties.

The declarant has nothing further to say.



Albert Zorko Abram

12 May, 2004

Date

60195896 v1



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Experiment: 197/6

SL7.15

Title: Microsized foam IP evaluation

Aim:

- ① Prepare a sample of the "D-Shira" formulation
- ② Review low temperature stability results to date

Experiment:

The following "D-Shira" formulation was prepared. Lot: SY- P70 replaced the 10% 114 polyol in the initial formulation.

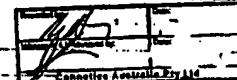
		Batch	
①	Microsized	99137	3.0 g
②	Nicotinic Acid -N-Diethyl	21063	2.0 g
③	Crotonic glycol	22583	9.0 g
④	Isopropyl alcohol	21242	4.5 g
⑤	Cellf alcohol	95529	1.6 g
⑥	Steric acid	21291	0.9 g
⑦	Lauroth -4	24645	4.7 g
⑧	Water	-	64.1 g
	1gollet P70	26071	5.0 g

Items ① to ⑦ were mixed at room temperature and formed clear solution.

Items ⑧ and ⑨ were added and the mixture was mixed to 50°C but a clear solution did not form.

On cooling this formed a thin gel/latex.

When the polyol was added the thin gel/latex gelled significantly forming a laminated surface latex and dissimilar to 30% 5105. Would this happen with polyol 14 I don't know.



SOLTEC RESEARCH

Innovation in Drug Delivery

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Manufacturing Dossier

Strictly confidential

Soltec Item description: 5% Minoxidil Mousse
Soltec Formula: F112/29/03
Soltec Batch Number: E126/10/01



Batch Record

Item	Quantity	Unit	Batch No.	Expiry Date	Notes
Phase 1					
1 Ethanol 100AG 22	22004	10.00	500.00	500.0	Reader Tare: 26.82
2 Polysorbate 60	21371	0.40	20.00	20.0	+ theoretical weight (2)
3 Stearyl alcohol	21364	0.50	25.00	25.0	
4 Cetyl alcohol	21365	1.10	55.00	55.0	
Phase 2					
5 Ethanol 100AG22	23004	43.845	2182.25	2185.7	Etanol added to correct for exp. loss
6 Butylated hydroxytoluene	21368	0.085	4.75	4.8	(exp. loss)
7 Purified Water	6144-02	31.410	1570.50	1582.2	(exp. loss)
8 Citric acid	21369	0.10	5.00	5.0	
9 Minoxidil	20105	4.75	237.50	237.8	Reader Tare: 1000.26
10 Lactic Acid (80%)	21363	1.00	50.00	49.9	+ tare weight = 4165.4
11 Propylene Glycol	21367	2.00	100.00	100.0	5165.66
Phase 3					
12 Propellant P70	20229	5.00	250.00	246.4	ethanol added to correct for exp.
13 Total		100.00	5,000.00		(total weight = 5.17 kg)

8 frommated